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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CROSS, LATOYA I	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/773,826	ROBACK ET AL.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-28* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on 5/13/2004. Claims 1-9, 11 and 12-28 are pending. Claims 12-24 are withdrawn from consideration.

Withdrawal of Rejections from Previous Office Action

- The anticipatory rejection over Yaremko et al is withdrawn in view of Applicant's incorporation of a flow cytometer, as the image acquisition system, into independent claims 1 and 25.
- The Double Patenting rejection over Application 10, 602,981 is withdrawn in view of Applicants' timely filed Terminal Disclaimer.

Terminal Disclaimer

The terminal disclaimer filed on 5/13/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application 10/602,981 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites that the image acquisition system is a camera. Claim 1, from which claim 11 depends, already defines the image acquisition system as a flow cytometer. Thus, claim 11 improperly redefines what is already set forth in claim 1. It is suggested that Applicants define the image acquisition system in claim 1 to be either a flow cytometer or a camera (i.e. in a Markusch grouping). Or, Applicants may delete claim 11.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2-6, 8, 11 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of Layne et al.

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606). The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, as recited in claims 1 and 25 (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filter is made of either beads or a porous gel material, as recited in claims 1, 3 and 4. The beads have a size of 10-100 microns, as recited in claim 5. See col. 6, lines 9-32. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims1, 8, 25 and 27 (col. 13, line 61 – col. 15, line 3). The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 11 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises

a pipette (402) and a robot arm (404), as recited in claim 1 (col. 13, lines 1-12). With respect to the washer recited in claim 2, Yaremko et al teach that washers (406, 410) contain liquids for rinsing or cleaning (col. 13, lines 23-28).

Yaremko et al fail to teach a flow cytometer in the system for image acquisitioning.

Layne et al is directed to an apparatus for automated testing of biological specimens. Layne et al teach that image acquisitioning in automated analyses allows detection of target individual cells and allows the collection of data to be observed by the user later (col. 14, lines 14-19). Layne et al teach that flow cytometry is suitable for image acquisition (col. 17, lines 34-39). It would have been obvious to one of ordinary skill in the art to modify the Yaremko et al reference by substituting the camera imaging system for a flow cytometry imaging system, as taught by Layne et al. In testing of blood specimens, such a modification would allow the user to detect and analyze individual blood cells.

5. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al and Layne et al, as applied above, and further in view of US Patent 5,603,899 to Franciskovich et al.

The disclosures of Yaremko et al and Layne et al are described above. Neither Yaremko et al nor Layne et al teach a vacuum system for separating the sample.

Franciskovich et al teach an apparatus for separating samples into their constituents. The reference teaches that both centrifuges and vacuums provide good means for separating multiple samples into their base constituents simultaneously. See col. 2, lines 25-31. Thus, it would have been obvious to substitute the centrifuge assembly of Yaremko et al with a vacuum

assembly as disclosed by Franciskovich et al to allow simultaneous separation of multiple samples and thus increase the sample processing time.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al and Layne et al, as applied above, and further in view of US Patent 6,008,040 to Datar.

The disclosures of Yaremko et al and Layne et al are described above. Neither Yaremko et al nor Layne et al teach the particular filter materials recited in claim 7.

Datar teaches efficient separation of cells, cellular materials and proteins. Specifically, Datar teaches separation devices such as bead columns. Further, Datar teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of Yaremko et al. These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Response to Arguments

5. Applicant's arguments filed 5/13/2004 have been fully considered but they are not persuasive. With respect to the Yaremko et al reference, Applicants first argue that the washers of Yaremko do not wash the assay sample while the sample is disposed within the filter vessel. In response, Applicants should note that in claims directed to an apparatus, per se, the function of the components is insufficient to impart patentability to the claims. Yaremko et al teach washers. The fact that the washers of Yaremko et al may not be disclosed as functioning

in the same manner as Applicants' washers is insufficient to impart patentability to the claims. See MPEP 2114.

Applicants also argue that the claims now recite that the presence of a flow cytometer as the image acquisition system. Applicants state that the secondary reference (Layne et al) does not teach that the flow cytometer is the digital image analysis system. In response, the Examiner disagrees. At col. 14, lines 14-19, Layne teaches that the image acquisition and analysis SLM detects individual cells within cell monolayers and collects observable data. Further, the image acquisition and analysis system comprises a digital image analysis system and motorized microscope stages. At col. 17, lines 57-61, Layne recites, "the automated image acquisition and analysis test instrument module comprises instruments selected from a flow cytometer, *inter alia*. Thus, contrary to Applicants' statement, the flow cytometer of Layne et al appears to be the image analysis system.

Applicants further argue that Layne et al require the use of a digital image analysis system with a motorized microscope stage, whereas the instant invention does not require a second detector instrument. In response, Applicants should note that the claims recite "comprising" language, which is open language that allows for the presence of components in addition to those explicitly recited. Nothing in the instant claims excludes the presence of an additional detector or imaging instrument.

Lastly, with respect to the Layne et al reference, Applicants argue that the image acquisition system of Layne is not disclosed as being able to detect agglutination interactions between the components and reagents of the assay mixture. Again, this limitation is directed to the function of the image acquisition system. Functional language does not limit the claims sufficiently to impart patentability. See MPEP 2114.

With respect to the rejections over Franciskovich et al and Datar, Applicants stated that the limitations of claims 7, 9 and 28 were not met by the references. However, Applicants failed to point out the supposed errors in the rejections or the reasons why the limitations were not met. Thus, the rejections are maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist

ARLEN SODERQUIST
PRIMARY EXAMINER

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